K073048

FEB 28

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter's Address:**	Alex Rapoport, CEO Arlozorov 41a, Rishon Le Zion, 75214 Israel
1. (b)	***Manufacturer Address:***	Scilex, Ltd. Arlozorov 41a Rishon Le Zion 75214, Israel
	Mfg. Phone:	972-3-950-6949
	Contact Person:	Alex Rapoport, CEO
	Date:	October 25, 2007
2.	***Device & Classification Name:***	Laser Handpiece Accessory System (Class 2), Product Code GEX, 21 CFR 878.4810 - Tradename of device: Peterio™ Universal Laser Scanning Handpiece
3.	***Predicate Device:***	DioScan Scanning Handpiece (K990014) MedArt 455/910 Series Scanner (K984339) Hexascan Handpiece (K901008)
4.	***Description:***	The Peterio™ Universal Laser Scanning Handpiece is an accessory for a legally marketed, compatible laser system. It is hand held device which attaches to the distal end of the laser system and delivers rapid scanning of the laser beam over a predetermined surface area. The Peterio has been designed for delivering the energy fluence equivalent to that of legally marketed compatible lasers, to a confined volume at a selectable tissue depth, while at the same time the Peterio exposes the tissue surface to less than 10% of the fluence of such lasers.
5.	***Intended Use:***	The Peterio™ Universal Laser Scanning Handpiece is intended to be used as an accessory to a compatible non-ablative 1064 nm laser and for its legally marketed, dermatological indications including: Removal of unwanted hair, for stable long term or permanent hair reduction on all skin types Fitzpatrick I-VI including tanned skin; Coagulation and hemostasis of sub-surface vascular lesions.
6.	***Comparison of Technological Characteristics:***	With respect to technology, the Peterio™ Universal Laser Scanning Handpiece is substantially equivalent to its predicate devices in that it is an accessory to a legally marketed laser system and scans the laser beam with rotating mirrors. It also has the same basic intended use as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Scilex, Ltd.
% Alex Rapoport
CEO
Arlozorov 41a
Rishon Le Zion
75214, Israel

Re: K073048
Trade/Device Name: Peterio™ Universal Laser Scanning Handpiece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 15, 2007
Received: October 29, 2007

Dear Alex Rapoport:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073048

Device Name: Peterio™ Universal Laser Scanning Handpiece

Indications For Use: The Peterio Universal Laser Scanning Handpiece is intended to be used as an accessory to a compatible non-ablative 1064nm laser and for its legally marketed, dermatological indications including: Removal of unwanted hair, for stable long term or permanent hair reduction on all skin types Fitzpatrick I-VI including tanned skin; Coagulation and hemostasis of sub-surface vascular lesions.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Milkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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